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CONNOLLY BOVE LODGE & HUTZ, LLP			EXAMINER	
P O BOX 2207			KUMAR, VINOD	
WILMINGTON, DE 19899			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,362	Applicant(s) CHARDONNENS ET AL.	
	Examiner Vinod Kumar	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,8-11,13,15,18,19,21,25,29,32,34,41,45,47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 21,25,34,41 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8-11,13,15,18,19,29,32,47 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of objections and rejections

1. Office acknowledges the receipt of Applicant's response filed on May 7, 2007, and August 31, 2007. Claims 1, 5, 8-11, 13, 15, 18, 19, 21, 25, 29, 32, 34, 41, 45, 47, and 49. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47, and 49 are examined in this Office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Objections to specification have been withdrawn in light of amendments to the specification filed in the paper of August 31, 2007. All previous claim objections not set forth below have been withdrawn in view of claim amendments filed in the paper of August 31, 2007. All previous claim rejections under 35 U.S.C. 112, 2nd paragraph, and 35 U.S.C. 102(b) are withdrawn in light of claim amendments filed in the paper of August 31, 2007. This action is made FINAL.

Election/restriction

2. Claims 21, 25, 34, 41, and 45, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/03/06. The restriction was made final in the Office action mailed on January 25, 2007.

This application contains claims 21, 25, 34, 41, and 45 drawn to inventions nonelected with traverse in the reply filed on 11/03/06. A complete reply to the final

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rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

3. Claims 1, 18 and 29 are objected due to following informalities:

In claims 1 and 29, it is suggested to insert --of the same species-- after "plant cell" in line 8 of claim 1, and after "plant" line 5 of claim 29.

Claim 18 is objected for missing an article "an" before "appropriate in line 5. The objection to claim 18 has been necessitated due to the claim amendment filed in the paper of August 31, 2007.

Appropriate corrections are required.

Double Patenting

4. Claims 1, 5, 8-11, 13, 15, 18, 19, 29, 32, 47 and 49 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 10, 11, 12, 15, 16, 19, 22, 23 and 24-27 of co-pending Application No. 11/251,208 ('208). Although the conflicting claims are not identical, they are not

patentably distinct from each other for the reasons of record stated in the Office action mailed on November 3, 2006.

Applicant's response filed in the paper of August 31, 2007 does not address issues related to double-patenting rejection. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 112

5. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47 and 49 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for drought, salt or low temperature tolerant transgenic plant cell, plant or a method of making said transgenic plant cell or plant comprising transformation of said plant cell with an ORSRP coding nucleic acid sequence encoding the protein of SEQ ID NO: 4, does not reasonably provide enablement for a transgenic plant cell, plant or a method of making said transgenic plant comprising (a) homologs of SEQ ID NO: 3 encoding proteins having less than 100% sequence to SEQ ID NO: 4, and (b) tolerance to an environmental stress associated with high temperature, metal, chemical, pathogenic and/or oxidative stresses. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the reasons of record stated in the Office action mailed on November 3, 2007. Applicants traverse the rejection in the paper filed on August 31, 2007.

Applicants argue that homolog is a nucleic acid that encodes a protein having an amino acid sequence with at least 80% identity to SEQ ID NO: 4. Applicants argue that specification teaches how to make conservative amino acid substitutions in a protein, and the screening a homolog with the specified homology and function is routine to those skilled in the art (response, page 8, lines 1-22).

Applicant's arguments were fully considered but were not found to be persuasive. Claims 1, 18, 19, 29, 47, and 49 are directed to homologs of SEQ ID NO: 3 encoding a protein which has 80% sequence identity to instant SEQ ID NO: 4. Further, claims 5, and 32 are directed to a nucleic acid sequence encoding a protein which has 90% sequence identity to SEQ ID NO: 4.

It is maintained that these claims encompass amino acid sequences having less than 100% sequence identity to SEQ ID NO: 4 and having abiotic stress tolerant property. An amino acid sequence with 80% sequence identity to the 143 amino acid long SEQ ID NO: 4 would comprise 28 amino acid substitutions in the amino acid sequence of SEQ ID NO: 4. An amino acid sequence with 90% sequence identity to the 143 amino acid long SEQ ID NO: 4 would comprise 14 amino acid substitutions in the amino acid sequence of SEQ ID NO: 4. Thus claims encompass amino acid sequences having unspecified amino acid changes in the amino acid sequence of SEQ ID NO: 4.

It is maintained that neither the state of related art nor the specification provide guidance on which region(s) protein SEQ ID NO: 4 can be altered without abrogating abiotic stress tolerance property. It is further maintained that neither the specification nor the related art provide guidance on the conserved (including signature pattern)

functional domains that are essential for the SEQ ID NO: 4 activity. It is further maintained that the specification and the related art fails to provide guidance on the amino acid residues within SEQ ID NO: 4 that are essential for maintaining a stable 3D structure of SEQ ID NO: 4. In this regard, it is important to note the teachings of Guo et al. who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, a sequence identity of 80-90% to SEQ ID NO: 4 would result in higher proportion of variants lacking abiotic stress tolerance property.

Applicants are reminded that the issue is *not* whether experimentation was required at the time claimed invention was made to determine how to isolate nucleotide sequences (homologs of SEQ ID NO: 3) encoding proteins which are variants or derivatives of SEQ ID NO: 4. Rather, the issue is whether the experimentation required was undue at the time the claimed invention was made, based upon the various factors previously discussed, and further outlined above.

It is also maintained that while the specification is enabled for salt, drought or low temperature tolerance property of SEQ ID NO: 4, however, the specification is not enabled for any biotic or abiotic stress property of instant SEQ ID NO: 4. See the last paragraph bridging the pages 11-12 of last Office action mailed on January 25, 2007.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed previously and further outlined above, it is maintained that undue experimentation would have been required by one skilled in the art at the

time the claimed invention was made to practice the invention commensurate in scope with these claims.

6. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47 and 49 remain rejected under 35 U.S.C. 112, first paragraph first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record as stated in the Office action of November 3, 2006. Applicants traverse the rejection in the paper filed on August 31, 2007.

Applicants argue that the amended claims recite 80% sequence identity to SEQ ID NO: 4 and exhibiting ORS RP activity. The specification provides motif domains defined by consensus sequences and represent common structure of the ORSRP proteins which correlates to the function of proteins (response, page 9, lines 8-11).

Applicant's arguments were fully considered but were not found persuasive. It is maintained that these claims encompass amino acid sequences having less than 100% sequence identity to SEQ ID NO: 4 and having abiotic stress tolerant property. An amino acid sequence with 80% sequence identity to the 143 amino acid long SEQ ID NO: 4 would comprise 28 amino acid substitutions in the amino acid sequence of SEQ ID NO: 4. An amino acid sequence with 90% sequence identity to the 143 amino acid long SEQ ID NO: 4 would comprise 14 amino acid substitutions in the amino acid sequence of SEQ ID NO: 4. Thus claims encompass amino acid sequences having unspecified amino acid changes in the amino acid sequence of SEQ ID NO: 4.

The specification does not describe the structures of Applicant's broadly genus, and further fail to correlate said structures to the function of abiotic stress tolerant property. Thus, there is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of a nucleic acid sequence encoding SEQ ID NO: 4.

The only species described in the specification is SEQ ID NO: 3 which encodes SEQ ID NO: 4. Thus one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 3 and 4 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing.

See in re Curtis (69 USPQ2d 1274 (Fed. Cir.2004), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not predict the operability of other species other than the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the art, reading the initial disclosure, would "instantly recall" additional species of the genus already "stored" in the minds, but if other members of the genus would not "naturally occur" to a person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

For at least these reasons and the reasons of record stated in the previous Office Action, the requirement for written description has not been met.

Claim Rejections - 35 USC § 103

7. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47 and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gan (Biochem. Biophys. Res. Comm., 187:949-955, 1992) in view of Valvekens et al. (PNAS, 85:5536-5540, 1998) and Grant et al. (Biochimica et Biophysica Acta, 1490:33-42, 2000) for the reasons of record stated in the Office action mailed on November 3, 2007. Applicants traverse the rejection in the paper filed on May 7, 2007.

Applicants argue that Gan, Valvekens et al. and Grant et al., alone or in combination do not disclose or teach all the claim limitations. Applicants further argue that it could not have been predicted that transforming a plant cell or plant with yeast glutaredoxin GRX2 coding sequence or related sequences would confer instantly claimed phenotype. It would have been only speculative whether a plant cell or plant transformed with yeast glutaredoxin GRX2 would exhibit increased tolerance to environmental stresses since yeast is not an art acceptable model for plant study (response, page 18, lines 7-19; page 19, lines 1-3).

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that it would have been obvious to one of the ordinary skill in the art to express a nucleic acid sequence encoding glutaredoxin protein of Gan et al. in any host including a plant host using any plant transformation method including the one taught by

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Valvekens et al. It is further maintained that given Grant et al. teach that glutaredoxin proteins (same as taught by Gan et al.) are implicated in protecting a cell subjected to an environmental stress, one of ordinary skill in the art would have been motivated to express Gan et al. nucleic acid sequence encoding glutaredoxin protein in any eukaryotic host cell including a plant cell to produce a transgenic plant cell which is regenerated into a stress-tolerant transgenic plant with reasonable expectation of success. It may be emphasized that was a routine practice in the art of plant molecular biology at the time the claimed invention was made to use a yeast expression system in screening cDNA libraries for isolating and establishing the function of unknown plant genes. Thus one of ordinary skill in art would have also been motivated to overexpress any useful yeast protein including yeast ORSRP of SEQ ID NO: 4 in a plant to obtain abiotic stress tolerant plant with reasonable expectation of success, and without any unexpected results.

It is further maintained that it would have been obvious to one of ordinary skill in the art to use Gan et al. nucleic acid encoding the glutaredoxin protein as a DNA marker in any DNA hybridization based technique, such as Southern blot or DNA dot blot analysis to identify stress-tolerant transgenic plant with reasonable expectation of success.

It may be emphasized that is routine in the art of plant molecular biology to use yeast expression system for screening for plant gene function, implying it would have been obvious for one of ordinary skill in the art to overexpress a well characterized

protein (e.g. yeast ORSRP) in a plant to obtain abiotic stress tolerance with reasonable expectation of success.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art would have arrived at the instantly claimed invention with reasonable expectation of success by combining the teachings of Gan et al., Valvekens et al., and Grant et al.

It is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For at least these reasons and the reasons of record stated in the previous Office Action, it is maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

8. Claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47 and 49 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-5444. The examiner can normally be reached on 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

